

REMARKS

Applicant has cancelled claims 1-79 herein without prejudice or disclaimer. New claims 80-108 have been added. No new matter has been added as a result of this amendment. Support for new claims 80-108 may be found throughout the specification.

Applicant's cancellation of claims 1-79 is not to be construed as an admission of the merits of the Office's position of record regarding patentability of the earlier claims of record. Applicant respectfully disagrees with the rejections presented in the office action of January 14, 2004. However, in an attempt to expedite examination and allowance of the claimed subject matter, Applicant has cancelled the previous claims without prejudice or disclaimer and herein submits new claims which clarify Applicant's invention.

The rejections presented in the office action of January 14, 2004, were based on several art references. However, none of these references disclosed the present invention, as clarified by the newly submitted claims. More specifically, Applicant's invention is directed to methods for improving the size or appearance of closed wounds by administering a therapeutically effective amount of a composition comprising a suitable pharmaceutical carrier and at least one non-steroidal anti-inflammatory agent such as a cyclooxygenase inhibitor, an NF- κ B inhibitor, a prostaglandin E2 inhibitor or some combination thereof. As defined in the specification at page 6, "[a] wound is 'closed' after an open wound has been reepithelialized." A wound is typically closed within 48-72 hours after injury. The methods of the present invention include the use of a thermal insulating material, a gel, a hydrogel, or a sponge along with administration of a non-steroidal anti-inflammatory agent such as a cyclooxygenase inhibitor, a NF- κ B inhibitor, or prostaglandin E2 inhibitor.

Previously the claims referred to "a method for improving the size and appearance of a *healed* wound." Applicants have not amended the scope of their claims as the definition of "healed wound" in the specification (see page 6) is synonymous with a "closed wound" as now used in the claims.

This invention is neither recognized nor appreciated in the references previously relied on by the Office, and therefore, these references should not be used as a basis for rejecting the newly submitted claims.

For example, Sibley, a reference previously relied on by the Office, discloses a preparation of “thixotropic gel, which is suitable for local treatment or control of hypertrophic cicatrisation in acne.” Sibley at p. 5. Specifically, Sibley discloses a preparation that treats “sebaceous accumulations, pustules, and papules as they may occur in Acne vulgaris.” Sibley at p.7. In addition, Sibley discloses that the preparation can be used “for the treatment of tinea versicolor, seborrheic dermatitis, as well as other disorders, which are associated with hyperplasia that has been brought about by infected sebaceous glands.” Sibley at p. 7.

Sibley teaches a preparation containing salicylic acid that can be used as an “exfoliant,” the mainstay treatment of acne. Specifically, salicylic acid is useful in treating acne because it causes the turn over of, shedding of or removes dead or dry cells that can obstruct pores, which leads to proliferation of bacteria and results in acne. See U.S. Patent No. 6,384,023. Thus, the type of “wound” Sibley teaches treating is a blocked pore “brought about by infected sebaceous glands.” This is not a closed wound because it never comprised a non-epithelialized layer. Sibley does not teach administering a composition to a closed wound to control inflammation and improve the size or appearance of a scar.

In contrast, the present invention, as clarified by the newly submitted claims, is useful with “closed wounds” or wounds that have grown or re-grown an epithelial barrier. Thus, while Sibley teaches use of a preparation for removing cells, the present invention teaches a method of using a composition to promote growth of cells.

Similarly, none of the other references previously relied on by the Office teach improving the size or appearance of a wound closed by re-growth of a epithelial barrier by administering a therapeutically effective amount of a cyclooxygenase inhibitor, a NF- κ B inhibitor or a combination of a cyclooxygenase inhibitor and a NF- κ B inhibitor. More specifically, Lee, U.S. Patent No. 5,552,162 neither discloses nor suggests inhibiting

cyclooxygenase activity, either directly or indirectly, to achieve improvement in the size or appearance of a closed wound. Singer, U.S. Patent No. 4,346,108, teaches system administration of ibuprofen *prior* to surgery, whereas the present invention is useful *after* a wound has closed. Allen, U.S. Patent No. 4,895,727, teaches a method for inducing a reservoir effect in skin and mucous membranes so as to enhance penetration and retention of topically applied pharmacologically active therapeutic and cosmetic agents. Allen fails to teach any methods for improving the size or appearance of a closed wound using therapeutically effective amounts of cyclooxygenase inhibitors or NF- κ B inhibitors. Boghosian, U.S. Patent No. 4,244,948, like Sibley, is directed to methods of treating acne and does not disclose any methods of treating closed wounds using non-steroidal anti-inflammatory inhibitors such as cyclooxygenase inhibitors.

SUMMARY

Applicant respectfully requests entry of new claims 80-108 for prosecution in this application. The Examiner is invited to contact the undersigned attorneys for Applicant via telephone if such communication would expedite the prosecution of this application.

Respectfully submitted,

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